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745 South 23rd Street
Second Floor
Arlington, Virginia 22202

In re Application of: ALVES et al.
U.S. Application No.: **10/586348**
PCT Application No.: PCT/FR2005/000093
International Filing Date: 14 January 2005
Priority Date Claimed: 15 January 2004
Attorney Docket No.: 0508-1167
For: METHOD FOR OVERPRODUCING A SPECIFIC RECOMBINANT PROTEIN WITH P.CINNABARINUS MONOKARYOTIC STRAINS

DECISION ON PETITION

This communication is responsive to the "Response to Notification of Defective Response" filed 28 May 2008, which has been treated as a petition under 37 CFR 1.181.

BACKGROUND

On 14 July 2006, applicant submitted national phase papers in the United States Designated/Elected Office (DO/EO/US). The papers provided PCT/FR2005/000093 as the international application number.

On 19 September 2007, the DO/EO/US mailed a *Notification of Corrected Papers under 35 U.S.C. 371 in the United States Designated/Elected Office (DO/EO/US)*, which indicates the following:

- This application clearly fails to comply with the requirements of 37 CFR 1.821-1.825. And requires, *inter alia*, an initial paper copy of the sequence listing.
- A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e).
- Substitute drawings in compliance with 37 CFR 1.84 because drawing figures contain text that is not in English (including, for example, a flow chart that was originally not in English that has been marked up to include the English text) see 37 CFR 1.84(p)(2) and 37 CFR 1.52(d)(1).

On 22 January 2008 applicant filed a response which includes:

- a copy of the sequence listing in computer readable form

- a paper copy of the sequence listing that consists of twenty-six (26) pages containing a list of eighteen (18) sequences ("twenty-six (26) page paper copy")
- a statement that the attached paper and computer readable copies have the same content, and introduce no new matter into the present application
- an instruction to enter the sequence listing into the application, and
- thirteen (13) sheets of substitute drawings (Figs. 1-12) in compliance with 37 CFR 1.84.

On 25 January 2008, the DO/EO/US mailed a first *Notification of Defective Response*, which indicates the application clearly fails to comply with the requirements of 37 CFR 1.821-1.825 and requires, *inter alia*, an initial paper copy of the sequence listing.

On 25 February 2008, applicant filed a response which alleged that the DO/EO/US had not acknowledged the 22 January 2008 response. In support, applicant provided a complete copy of the 22 January 2008 response and requested that the 22 January 2008 response be considered.

On 28 April 2008, the DO/EO/US mailed a second *Notification of Defective Response*, which indicates the following:

- Applicant's response was filed 10/17/2006.
- A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content does not comply with 37 CFR 1.822 and/or 1.823, as indicated on the attached copy of the marked-up "Raw Sequence Listing." Applicant must provide a substitute computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written sequence listing and, where applicable, includes no new matter.

On 28 May 2008, applicant filed a response which alleged that the marked-up "Raw Sequence Listing" was not received; however, applicant indicated that the response was prepared after reviewing the marked-up document using the Patent Application Information Retrieval (PAIR) system.

DISCUSSION

Upon investigation, the record reveals that a paper copy of the sequence listing was provided to the DO/EO/US by the International Bureau. In accordance with 37 CFR 1.821(c), the initial submission of the international application contained disclosures of sequences and contained, as a separate part of the disclosure, a paper copy of the sequence listing which consists of twenty-three (23) sheets containing a listing of sixteen sequences ("initial paper copy"). Thus, the requirement that applicant provide an initial paper copy of the sequence listing made in the 19 September 2007 *Notification of Corrected Papers under 35 U.S.C. 371 in the United States Designated/Elected Office (DO/EO/US)* was in error insofar as the initial paper copy of the sequence listing was received from the International Bureau.

The 25 January 2008 *Notification of Defective Response* is hereby VACATED because it was mailed prematurely, i.e., before the validation report for the 22 January 2008 computer readable form was completed.

In accordance with 37 CFR 1.821(e) the initial paper copy of the sequence listing must also be submitted in computer readable form that is in compliance with 37 CFR 1.824. In accordance with 37 CFR 1.821(f) a statement that the paper copy and the computer readable copy are the same must be submitted with the computer readable form. Applicant has not submitted a computer readable form of the initial paper copy of the sequence listing or a statement that the sequence listing information recorded in computer readable form is identical to the initial paper copy of the sequence listing. The computer readable form and statement submitted by applicant on 22 January 2008 are not submitted with regard to the initial paper copy, but instead refer to the twenty-six (26) page paper copy.

For reasons above, the copy of the sequence listing in computer readable form, the twenty-six (26) page paper copy of the sequence listing, and the statement received 22 January 2008 fail to comply with 37 CFR 1.821(e) and are not a proper response to the 19 September 2007 *Notification of Corrected Papers under 35 U.S.C. 371 in the United States Designated/Elected Office (DO/EO/US)*.

As a separate issue, the copy of the sequence listing in computer readable form submitted by applicant on 22 January 2008, when treated as a preliminary amendment, remains deficient because the computer readable form of the 22 January 2008 sequence listing contains errors (see attached 06 February 2008 validation/error report). Should applicant choose to submit a substitute computer readable form of the twenty-six (26) page paper copy of the sequence listing, the substitute computer readable form should be clearly distinguished from the computer readable form of the initial paper copy and the requisite statement should clearly identify the substitute computer readable form and relevant paper copy of the sequence listing.

CONCLUSION

The petition is **GRANTED to the extent** that the DO/EO/US has not previously notified applicant that a computer readable form of the initial paper copy of the sequence listing has not been received and that there is an inconsistency among the initial paper copy of the sequence listing, the computer readable form, and the twenty-six (26) page paper copy of the sequence listing.

Applicant is given **ONE (1) MONTH** from the mail date of this decision to provide a computer readable form of the initial paper copy of the sequence listing and a statement that the sequence listing information recorded in the computer readable form is identical to the initial paper copy of the sequence listing, in accordance with 37 CFR 1.821. Extensions of time may not be obtained under 37 CFR 1.136(a).

Correspondence with respect to this matter should be addressed to Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, with the contents of the letter marked to the attention of the Office of PCT Legal Administration.

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PCT Special Program Examiner
Office of PCT Legal Administration
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Facsimile: (571) 273-0459

Bryan Lin
PCT Legal Examiner
Office of PCT Legal Administration

Attachment: Validation/Error Report (regarding 22 January 2008 CRF), 11 pages

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Sequence Listing could not be accepted due to errors.

See attached Validation Report.

If you need help call the Patent Electronic Business Center at (866) 217-9197 (toll free).

Reviewer: Anne Corrigan

Timestamp: [year=2008; month=2; day=6; hr=16; min=4; sec=4; ms=286;]

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****

Reviewer Comments:

(from Sequence 1)

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The "125" above needs to be directly under "Gly" above it.

****

Validated By CRFValidator v 1.0.3

Application No: 10586348 Version No: 1.0

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Output Set:

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Finished: 2008-02-06 11:19:32.430
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Total Warnings: 13
Total Errors: 5
No. of SeqIDs Defined: 18
Actual SeqID Count: 18

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SEQUENCE LISTING

<110> ALVES, ALEXANDRA M.C.R.
RECORD, ERIC
LOMASCOLO, ANNE
SIGOILLOT, JEAN-CLAUDE
ASTHER, MARCEL
WOSTEN, HAN A.B.

<120> METHOD FOR OVERPRODUCING A SPECIFIC RECOMBINANT PROTEIN
WITH P. CINNABARINUS MONOKARYOTIC STRAINS

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<151> 2005-01-14

<150> FR 04/00366
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Cys His Ile Asp Phe His Leu Asp Ala Gly Phe Ala Val Val Met Ala
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Tyr His Ser His Leu Ser Thr Gln Tyr Cys Asp Gly Leu Arg Gly Pro
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Phe Val Val Tyr Asp Pro Asn Asp Pro His Ala Ser Leu Tyr Asp Ile
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